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(2015)

Can larger-bodied cemented femoral components reduce periprosthetic fractures? A biomechanical study.

Archives of Orthopaedic and Trauma Surgery, 135(4), pp. 517-522.

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The final publication is available at Springer via
<http://dx.doi.org/10.1007/s00402-015-2172-3>

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<http://doi.org/10.1007/s00402-015-2172-3>

Can larger bodied cemented femoral components reduce periprosthetic fractures?

A biomechanical study.

Abstract:

Introduction: The risk for late periprosthetic femoral fractures is higher in patients treated for a neck of femur fracture compared to osteoarthritis. It has been hypothesised that osteopenia and consequent decreased stiffness of the proximal femur are responsible for this. We investigated whether a femoral component with a bigger body would increase the torque to failure in a biaxially loaded composite Sawbone model.

Material and methods: A biomechanical bone analogue was used. Two different body sizes (Exeter 44-1 vs 44-4) of a polished tapered cemented femoral stem were implanted by an experienced surgeon in 7 bone analogues each and internally rotated at 40°/s until failure. Torque to fracture and fracture energy were measured using a biaxial materials testing device (Instron 8874, MI, USA). The data were non-parametric and therefore tested with the Mann-Whitney U-test.

Results: The median torque to fracture was 156.7 Nm (IQR 19.7) for the 44-1 stem and 237.1 Nm (IQR 52.9) for the 44-4 stem ($p=0.001$). The median fracture energy was 8.5J (IQR 7.3) for the 44-1 stem and 19.5J (IQR 8.8) for the 44-4 stem ($p=0.014$).

Conclusions: The use of a large body polished tapered cemented stems for neck of femur fractures increases the torque to failure in a biomechanical model and therefore is likely to reduce late periprosthetic fracture risk in this vulnerable cohort.

Word count: 219/300

Keywords: bigger body stem; periprosthetic fracture; fracture load; stress shielding; biomechanical study; sawbone model

Ethics approval: As this is a sawbones study, Ethics approval was not required

Acknowledgement: An Exeter 44-4 stem was made available by Stryker inc. for this study, no other form of support was received. The study was funded by the Queensland University of Technology.

Introduction:

The increasing age of people in western society is unfortunately accompanied with an increasing incidence of displaced neck of femur fractures (NOF). Modern medical science has spent many resources in studying the treatment options for these fractures. There is more and more evidence that cemented femoral components outperform uncemented components in patients with a neck of femur fracture, with less pain, less complication rates, better functionality and with the same or even lower mortality rates. [1-5] However some complications are still associated with this treatment option. There is an increased risk of late peri-prosthetic femoral fracture in patients undergoing surgery for a fractured neck of femur for cemented and uncemented femoral components compared to patients who receive the same components electively for hip arthritis. [6-8] The literature on the true prevalence of periprosthetic fractures of cemented and uncemented stems is difficult to interpret because of heterogeneity in patient population and different end points in the cohorts but has been reported to be up to 3.5% at ten years. [9-11]

Patient suffering from a NOF often have capacious canals and osteopenic bone. [12,13] We believe this results in a reduction of torsional stiffness in the proximal femur, that makes it susceptible to torsional loads [14].

The torsional mode of failure matches the findings of Lindahl et al. and Young et al. [15,16], who showed that 82%-90% of periprosthetic proximal femur fractures were of the Vancouver B1 and B2 type,[17] that are associated with a spiral fracture pattern.

We hypothesize that increasing the stiffness of the proximal femur with a larger body cemented implant will increase both the torsional load to failure and total energy to fracture.

Materials and Methods:

Ethics approval was not required for this bone analogue study. Power analysis using figures obtained for the 44mm offset stem in a previous Sawbones study [18] with an expected difference of 30Nm,

SD of 18, power of 80% and significance level of 5% indicated that a minimum of 7 femurs were required in each group.

Fourteen bone analogues, divided into two groups of seven, (Sawbones medium left femur model 3403; Pacific Research Laboratories, Vashon WA USA) were prepared for implantation of an Exeter cemented femoral component (Stryker Orthopedics, Mahwah, NJ). Two femoral stems were used, the Exeter 44 no. 1 stem (Stainless steel 165 gram, standard proximal body) and the Exeter 44 no.4 stem (Stainless steel 215 gram, large proximal body) (Fig. 1). All implant constructs were prepared by an experienced orthopaedic surgeon (BG). A standard femoral neck cut was made approximately 1cm proximal to the lesser trochanter, using a premade cutting guide to standardise the neck cuts. The bone analogues were broached using the appropriate broaching rasp for the stem. Broaching was performed to allow the stem to seat with the middle marking at the level of the neck cut (Fig. 2).

A distal cement plug (Stryker 13-17mm Artisan plug, Stryker Orthopedics, Mahwah, NJ) was introduced to sit just distal to the tip of the implant. The implant was then cemented with the use of a stem centraliser into the Sawbone using 2 mixes of Simplex cement (Stryker Orthopedics, Mahwah, NJ). The distal femoral condyle was resected 40mm in the supracondylar region to allow the femur to fit within the testing mechanism.

The proximal femur was attached, at the centre of rotation of the implant head, by means of a hydraulic clamp (Fig. 4) The center of the femoral head and intercondylar notch (located by the longitudinal hole in the bone analogue) were positioned in the vertical loading axis of the machine (Instron 8874) (Fig. 3). Distally the femur was fixed with Paladur dental acrylic (Heraeus-Kulzer GmbH, Wertheim, Germany), prepared as per manufacturer's instructions.

The femurs were tested in a combined compression force with torque to replicate clinically observed fracture patterns in cadaveric and analogue femurs. Clinical fractures are typically spiral in nature with a crack starting angle more than 45 degrees indicating both torque and compressive forces

being applied at fracture initiation. In a single leg stance the resultant force at the hip are approximated by $F = 2.5 \times BW$, where body weight was assumed to be 80kg giving a compressive force of 2000N. [19] A preload of 2Nm in the internal rotation direction and 2kN of compression was applied. The compressive load was then maintained and the implant internally rotated 40° in one second in order to simulate falling with internal rotation with a single leg stance. The angle of 40° was chosen to ensure that fracture had occurred fully (Figure 5).

Fracture torque was defined as the maximum torque measured. Fracture energy was calculated by numerically integrating the torque and angle measurements against time. All calculations were calculated with Matlab 2011(b) (Mathworks, USA) and statistical analysis performed using IBM SPSS for Windows version 21 (IBM Corp, released 2012, Armonk, NY). Normality testing indicated that the data was not normally distributed and so non-parametric methods were used for data analysis (Mann-Whitney U-test for comparisons). Accordingly, summary statistics are presented as medians and interquartile ranges (IQR). Boxplots are also presented. The primary endpoint was fracture torque, with fracture energy as the secondary endpoint. The significance level was set at 5%.

Results:

In all samples, the fracture pattern produced was the same as commonly observed in clinical practice. They are consistent with unstable fractures occurring around previously well fixed implants - a Vancouver B type periprosthetic fracture, with fracture around the previously well fixed stem resulting in a loose implant. [20,21] In all of our samples, the fracture propagated from the posterior proximal femur in the calcar and metaphyseal region, and spiralled distally into the diaphysis to exit close to the tip of the stem. A varying degree of fracture comminution was produced.

The median torque to fracture was 237.1Nm (IQR 52.9) for the 44-4 stem, which was statistically significantly higher than the mean torque to fracture for the 44-1 stem of 156.7Nm (IQR 19.7) ($p=0.001$, Mann-Whitney U-test) (Figure 6). The median fracture energy was 19.5J (IQR 8.8) for the

44-4 stem, statistically significantly higher than for the 44-1 stem of 8.5J (IQR 7.3) ($p=0.014$, Mann-Whitney U-Test) (Figure 7).

Discussion:

Patients treated with a cemented femoral stem for a fractured neck of femur have an increased risk of periprosthetic fracture when compared to hip arthritis patients. Bone quality in this cohort is often compromised due to osteoporosis and large capacious canals [8,9]. Stiffness of the proximal femur is reduced and this makes these femurs more susceptible for periprosthetic fractures as typically there isn't a corresponding reduction in loads to match the reduction in stiffness. A larger femoral implant can reduce this risk, as this study showed, by increasing the torsional stiffness of the proximal femur.

Fractures in the proximal femur occur when the bone is strained beyond its capacity. In a healthy young adult, bone remodels to increase stiffness under external stimulus such as weight training. In the elderly where the osteogenic potential is much lower, the likelihood of exceeding the strain limit is dramatically increased, as seen in greater fracture risk in this cohort. In structural loading scenarios, such as buildings, stiffer materials are used to prevent failure/fracture, which in a clinical sense translates to implanting a stiffer femoral component. The easiest option to increase the proximal femur stiffness is to use an implant with a larger proximal body.

Selection of the most appropriate femoral implant size is a clinical compromise between stress shielding and avoiding fractures in any patient. [22] The cumulative percent mortality in this patient group is reported as between 73.8% and 92.0% for partial hip replacement (58.4% for conventional total hip replacement). [23] Increasing the proximal stiffness in these elderly patients and hereby increasing the mean torque to fracture by 1.7 times as shown in this study seems more important than the long-term risk of stress shielding due to an immediate fracture risk reduction and the decreased 10 year life expectancy of this patient cohort.

The femoral shaft should not be broached aggressively in fractured neck of femurs. Aggressive broaching will lead to removal of cancellous bone (which is required for cement digitisation) and lead to an increased risk of intra-operative fracture. Our study does suggest that surgeons should not undersize the stem relative to the broach that is first stable in the canal or they will increase the risk of periprosthetic fracture.

There are a number of factors that have been shown to influence fracture behaviour of cemented stems. Erhardt et al [24] showed that a cemented double polished tapered stem (CPT Zimmer) when loaded to failure resulted in a significantly different fracture pattern to a triple tapered stem (C-stem). They showed that the fracture pattern was more around the body of the double tapered stem. This result is consistent with the fracture pattern seen in our work and that described by Morishima. [18]

In one of our previous studies [18] we showed that the length of an implant has an influence on the load to failure. A shorter implant has a lower load to failure compared to a stem with a similar proximal geometry. Morishima showed a decrease in torque of 16% for the shorter stem compared with the standard length size 1 stem. This difference was hypothesised to be due to a difference in the stiffness of the construct and the energy absorbed by the implant prior to fracture.

Our findings in this current study showed that the body size of the implant significantly affects the load to fracture in stems of the same length. A size 4 (larger bodied) stem of the same length (150mm) and offset (44mm) as a size 1 (small bodied) stem showed a 51% increase in torque to fracture. Increasing the volume of an implant will increase the rigidity of the proximal femur and will influence bone remodelling after implantation as noted by Pepke et al. [25] Their study supports the hypothesis that larger implants will lead to less physiological bone remodelling. In a younger population of patients undergoing primary THR the use of less bulky implants will lead to better long term bone remodelling. In the elderly patients undergoing prosthetic treatment for femoral neck fracture we believe that the protection against periprosthetic fracture conferred by larger bodied

implants outweighs any longer term concerns about bone remodelling and stress shielding in the long term.

The biomechanical model used in this study controlled the moment and the axial force through a validated saw bone model. We tested 7 saw bones in each group. Because all composite saw bones are similarly manufactured and are proven to have identical biomechanical properties no larger groups are needed. The only variation between the test object is created by the protocolled implantation technique and positioning in the test model. All fractures generated by the model resulted in a consistent Vancouver B2 fracture (unstable fracture around a previously well fixed implant) type proving that it is an accurate representation of the fracture mechanism.

[20,21,16,15,18]

The current study was limited by its design. Firstly the in vitro biomechanical model used in this experiment has some limitations. [26] Is not an osteoporotic bone model, but the representation of a normal femoral bone in a healthy young male. This model was used because at the time of testing there was no validated bone analogue available for osteoporotic bone and cadaveric bone was not available. We predict that an osteoporotic model would show a lower fracture energy for both stem sizes, but expect an amplification of the difference between the two due to the now even larger influence of the increased stiffness of the larger body size implant. [13] Secondly in our model we discarded the influence of the soft tissue envelope. In an in vivo model several muscle groups would counter the internal torsion force applied in the model. This would potentially influence the direction of force and the fracture pattern. A third limitation is that in the model the torsional load applied only extends to the distal femur while in a in vivo model it is unclear how far down the load would extend.

The results of this study indicate that the use of a large body cemented stem could reduce late periprosthetic fracture rates in this frail elderly population. Further research is required to confirm these findings in a cadaveric or osteopenic bone analogue model.

Figures:

Fig. 1 The left stem shown is an Exeter 44-1 stem, the right stem shown is the 44-4. Notice the increased body size



Fig. 2 Example of how a stem is fitted in the composite sawbone. The three markings on the stem can be used to determine the position of the stem. *Reprinted from J Arthroplasty, 29(5), Morishima et al, Periprosthetic fracture torque for short versus standard cemented hip stems: an experimental in vitro study, pages 1067-71, Copyright (2014), with permission from Elsevier*



Fig. 3 The testing mechanism. The composite femur and stem are fitted in the Instron. *Reprinted from J Arthroplasty, 29(5), Morishima et al, Periprosthetic fracture torque for short versus standard cemented hip stems: an experimental in vitro study, pages 1067-71, Copyright (2014), with permission from Elsevier*

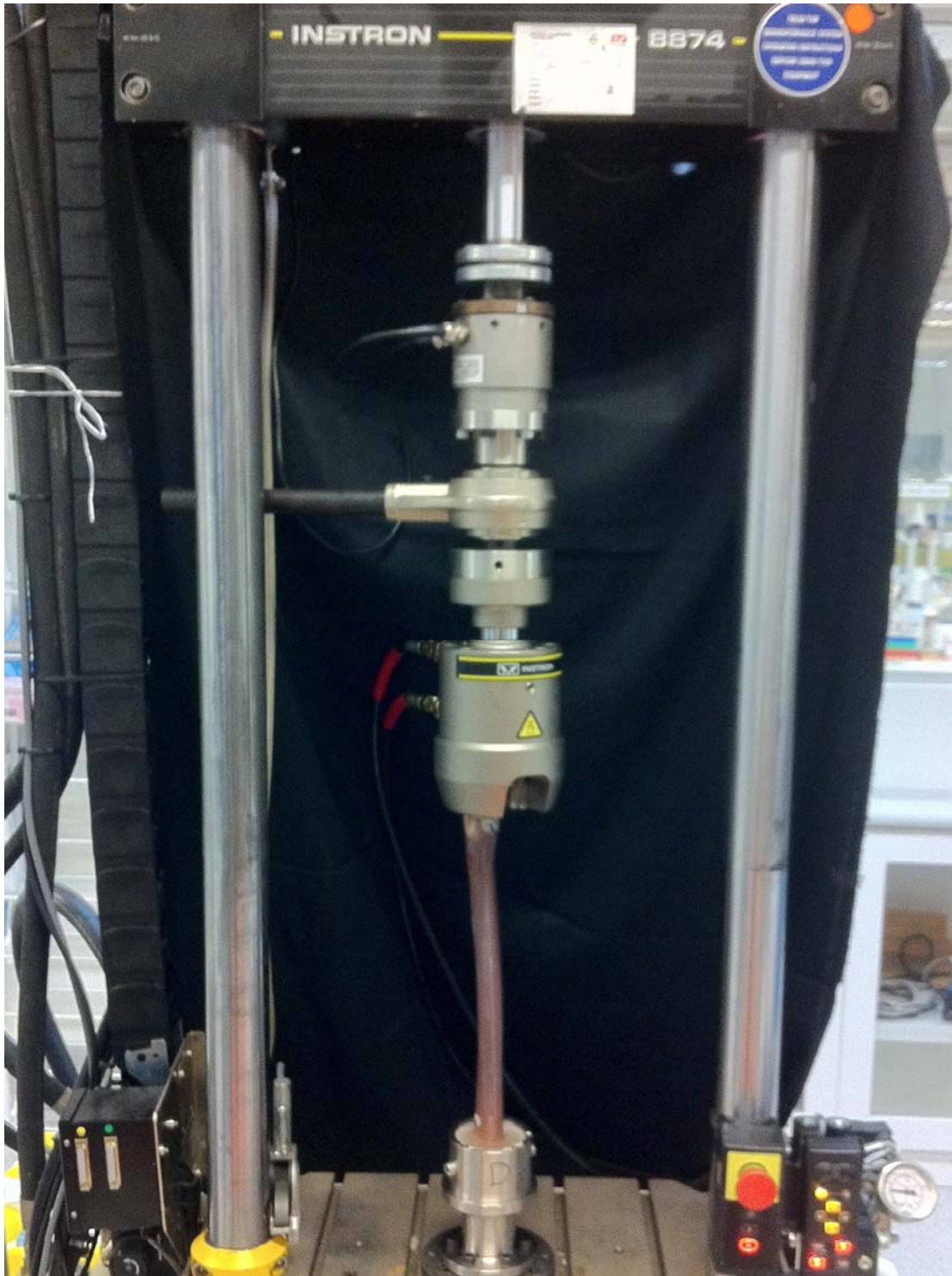


Fig. 4 The femoral head and intercondylar notch is located in the vertical loading axis of the machine to replicate the natural loading axis of the femur. The proximal femur is attached, at the centre of rotation of the implant head, by means of a hydraulic clamp. *Reprinted from J Arthroplasty, 29(5), Morishima et al, Periprosthetic fracture torque for short versus standard cemented hip stems: an experimental in vitro study, pages 1067-71, Copyright (2014), with permission from Elsevier*



Fig. 5 Example of the fracture pattern of an Exeter 44-4 stem created by our testing mechanism



Fig. 6 Boxplot of torque measured (Nm) at fracture for each of the implants

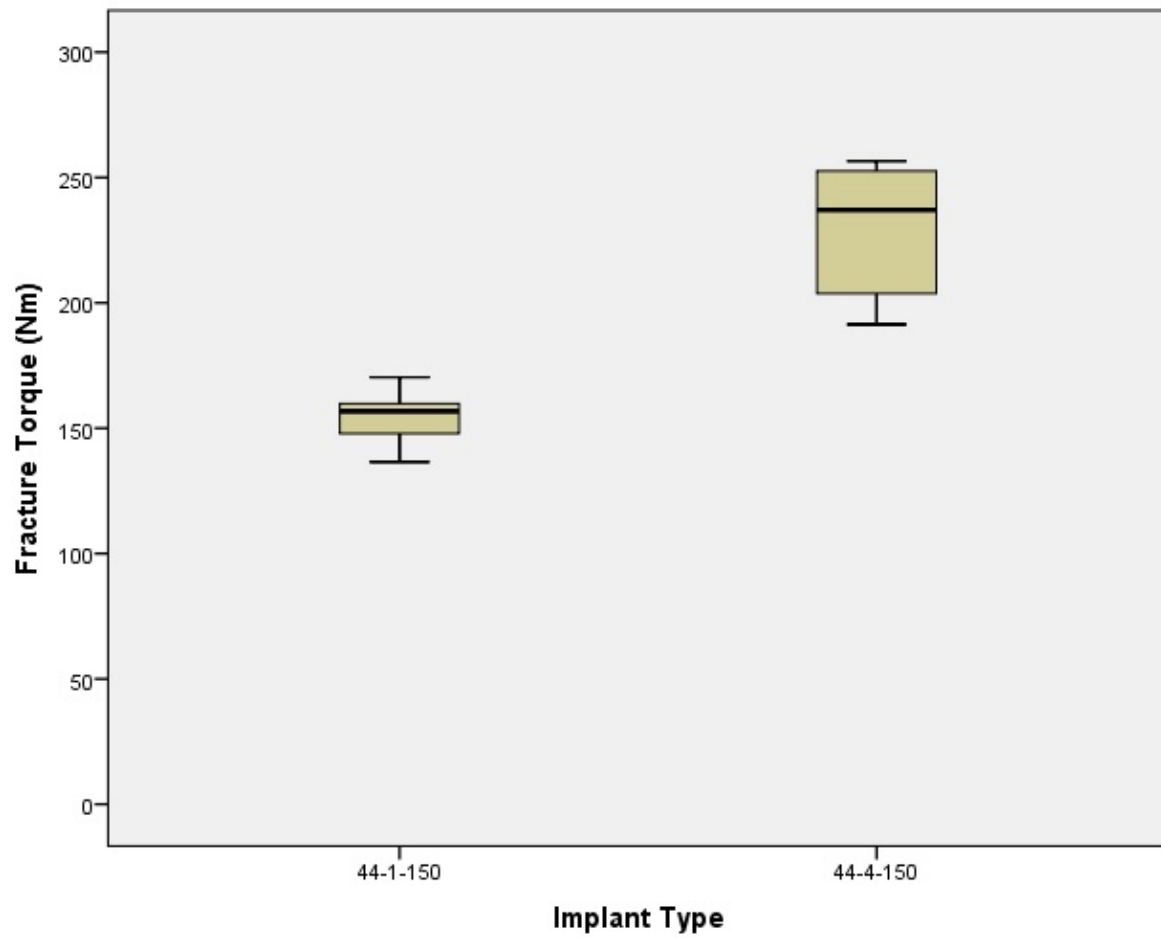
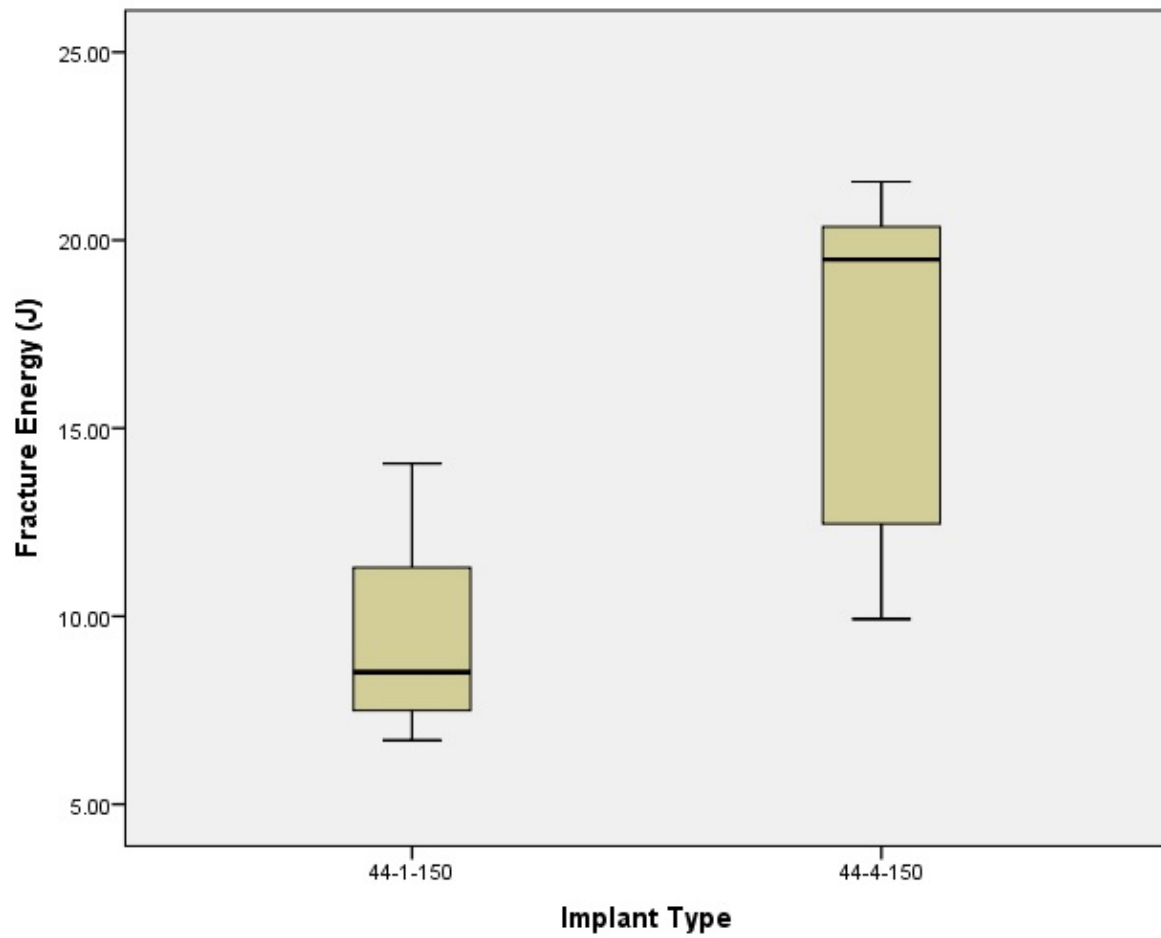


Fig. 7 Boxplot of fracture energy (J) measured at fracture for each of the implants



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